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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,856	07/25/2001	David H. Mack	003848.00091	4786

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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/911,856

Applicant(s)

MACK, DAVID H.

Examiner

Channing S Mahatan

Art Unit

1631

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112 2<sup>nd</sup> Paragraph Rejection.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-9, 106 and 107.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☒ The drawing correction filed on 02 May 2003 is a) ☒ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☒ Other: See Continuation Sheet

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PRIMARY EXAMINER  
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AC11631

Continuation of 10. Other: Claims 10-105 have been cancelled. Applicants argue "The art of statistics was well developed at the time the application was filed. One skilled in the art of statistics would have been readily able to analyze a cluster map to generate a gene network of causal models using the specification as a guide and the knowledge of how to perform analysis methods." Further, Applicants reference Joreskog et al. as teaching how to generally perform the LISREL method. While it is acknowledged Joreskog et al. teaches the general LISREL approach, it is the absence of specified parameters and assumptions for the general LISREL approach that fails to enable the claimed method. Joreskog et al. lists several parameters that are used to describe the measurement properties (validities and reliabilities) of the observed variables and the causal effects and the amount of unexplained variables (page 130, line 28 to page 132, line 21). However, absent from Joreskog et al. and the instant specification is an indication of what these parameters represent in relation to the analysis of gene cluster map and the generation of gene network causal models. Further, Joreskog et al. states "For most of our models we will consider the identification problem on a case-by-case basis" (page 134, lines 1-2) and does not disclose specified parameters and assumptions for gene network causal models to be utilized in the general LISREL approach. An individual skilled in the art would not have been informed as to what to do or how to adapt programs known in the art unless some type of specific procedure is set forth (i.e. specified parameters and assumptions) for gene network causal models. For example, refinement of LISREL (i.e. develop/identify parameters and assumptions) would be required to analyze the gene expression information provided by Schena et al. to generate gene network causal models. In the absence of sufficient guidance, further refinement is considered undue experimentation. Additionally, no gene network causal models are generated from the experimental work in the specification. One practicing the method as claimed would have to use his or her own inventive skill or ingenuity beyond that to be expected of one of ordinary skill in the art to adapt the known statistical techniques to this particular problem (invitation to experiment); namely generating a gene network causal model from cluster map. It should be noted Applicants arguments have been directed to LISREL, however, only claim 9 is limited to LISREL. Applicants arguments are therefore unpersuasive and the rejection of claims 1-9, 106, and 107 under 35 U.S.C. 112 1<sup>st</sup> Paragraph (Lack of Enablement) are maintained for reasons of record.